REMARKS/ARGUMENTS

Claims 1-4 and 7-20 are pending in the application. Claims 5-6 are canceled without prejudice. New claim 20 is added. Claim 1 is amended.

Claim 1 is amended to include the limitations of the original claims 5 and 6, and therefore the amendment is supported by those claims. Support for new claim 20 can be found in, for example, applicant's specification at page 19, lines 2-3.

Reexamination and reconsideration of the application are respectfully requested.

IDS DOCUMENTS

Applicant is submitting herewith the following IDS documents:

1. U.S. Patent 6,152,909

2. U.S. Patent 5,879,324

3. U.S. Patent 4,068,659

4. U.S. Publication No. 2001/0,007,922

5. Article "Percutaneous Aspiration Thromboembolectomy" from "Radiology" 156, 61-66 (July, 1985).

Consideration of those documents is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-17 and 19 are rejected under 35 USC 103(a) as obvious over Douk (US 2005/0027236) in view of Noriega (US 2005/0119615). Claim 18 is rejected as obvious over Douk in view of Noriega and Ha (US 6,159,195). Among the rejected claims, claims 5 and 6 are canceled and therefore, the rejections of those claims are moot.

For the remaining claims 1-4 and 7-19, applicant traverses the rejections and amends clam 1 to clarify that claim 1 patently distinguishes over the cited art. In particular, amended claim 1 recites:

> An aspiration catheter for removing by aspiration a substance from a living body comprising:
>
> a main shaft including a distal shaft and a proximal shaft, wherein an aspiration lumen for removing the substance by aspiration is disposed in the distal shaft and the proximal shaft;
>
> a guidewire shaft disposed at the distal region of the distal shaft, the guidewire shaft having a guidewire lumen into which a guidewire is insertable, the guidewire lumen being disposed in the guidewire shaft;
>
> a hub provided at the proximal end of the proximal shaft, the aspiration lumen extending to the hub; and
>
> a detachable core wire disposed in the aspiration lumen;
>
> wherein the relationship $0.4 \leq R1/R2 \leq 0.7$ is satisfied, wherein R1 is a maximum outer diameter of the core wire, and R2 is a minimum inner diameter of the aspiration lumen located on the distal side of the hub.

Thus, the invention of claim 1 provides a aspiration catheter having a main shaft that includes distal and proximal shafts. An aspiration lumen is disposed in the distal and proximal shafts. As shown in applicant's FIG. 1, an exemplary device includes main shaft 102, which includes distal shaft 103 and proximal shaft 104. Aspiration lumen 100 is disposed within main shaft 102, and more specifically, within distal shaft 103 and proximal shaft 104 (page 12, lines 4-23; FIGS 1-3).

The aspiration catheter satisfies a relationship $0.4 \leq R1/R2 \leq 0.7$, where R1 is the maximum outer diameter of the core wire, and R2 is the minimum inner diameter of the aspiration lumen located on the distal side of the hub.

The art of record does not disclose or suggest the limitations "an aspiration lumen for removing the substance by aspiration is disposed in the distal shaft and the proximal shaft" (the "aspiration lumen" limitations) and "the relationship $0.4 \leq R1/R2 \leq 0.7$ is satisfied, wherein R1 is a maximum outer diameter of the core wire, and R2 is a minimum inner diameter of the aspiration lumen located on the distal side of the hub" (the "diameter" limitations).

Concerning the "aspiration lumen" limitations, Douk discloses an aspiration catheter having a main shaft 105 for placing therein an aspiration lumen 107 (paragraph 25; FIG. 1), tubular elements 102, 104, and a distal segment 117 for

placing therein a guide wire (paragraph 0045; FIG. 1). The action identifies tubular elements 102 and 104 as proximal and distal shafts comprising the main shaft. That assertion is inaccurate. In Douk, aspiration lumen 107 is disposed within main shaft 105, and not tubular elements 102 and 104 (paragraph 25; FIG. 1). Lumen 114 is disposed within tubular member 102, and lumen 116 is disposed within tubular member 104. Lumens 114 and 116 are for placement of a guide wire, and not an aspiration lumen (paragraph 0045; FIG. 1).

Thus, Douk fails to teach or suggest an aspiration lumen for removing the substance by aspiration that is disposed in the distal and proximal shafts. Noriega and Ha do not remedy this deficiency. Noriega is directed to a hollow guidewire for removing tissue from a body lumen (Abstract) that includes a unitary elongated member 14 (FIG. 1), and does not teach or suggest a main shaft comprising distal and proximal shafts, and an aspiration lumen disposed within the distal and proximal shafts. Ha likewise teaches a unitary elongated member 114 (FIG. 1).

Moreover, concerning the "diameter" limitations, the Action does not argue that the cited art teaches those limitations. In reference to the original claims 5 and 6, which recite the "diameter" limitations, the Action argues that the "diameter" limitations are obvious because "the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art." However, as discussed above, the cited art does not teach or suggest the device provided by claim 1. Accordingly, the Action's argument cannot stand because the "the general conditions of a claim" are not disclosed in the cited art, and the "diameter" limitations are not ascertainable or foreseeable from the cited art.

Since the diameters required by the "diameter" limitations are not ascertainable or foreseeable from the cited art, the cite art cannot obviate claim 1 reciting those limitations.

For these reasons, claim 1 and claims 2-19 dependent therefrom are not obvious over Douk in view of Noriega and/or Ha. The rejections of claims 1-19 under 35 USC 103 should therefore be withdrawn.

CLAIM 1 IS PATENTABLE OVER THE IDS DOCUMENTS

The claims of present invention patently distinguishes over the IDS documents submitted herewith. In the interest of expediting the prosecution process, Applicant notes that claim 1 of present invention patently distinguishes over Bagaoisan (U.S. Patent 6,152,909) and von Hoffmann (U.S. Patent 5,879,324).

Von Hoffmann is generally directed at a low profile catheter shaft configuration for incorporation into any of a variety of catheters. The shaft comprises an inner collapsible tube coaxially disposed within an outer tube. The device includes a first and a second side-by-side lumens with a movable wall extending axially therebetween. The first lumen may occupy more than half of the inside diameter of the shaft such as during advancement along a guidewire, and the second lumen may occupy more than half of the inside diameter such as following withdrawal of the guidewire and during inflation of a balloon. (Abstract).

Von Hoffmann does not teach or suggest, at least, the required "diameter" limitations. In particular, von Hoffmann does not teach or suggest the required relationship $0.4 \leq R1/R2 \leq 0.7$, where R1 is a maximum outer diameter of the core wire, and R2 is a minimum inner diameter of the aspiration lumen located on the distal side.

Moreover, applicant suggests that a person of ordinary skill in the art could not have derived the required ratio of claim 1 from von Hoffman because Von Hoffmann and the present invention are directed at different types of devices. Von Hoffmann is generally directed at an "over-the-wire" type catheter. FIGS. 6 and 7 illustrate that the guidewire 40 and the column support 42 are present over the whole length of catheter. Von Hoffmann provides "a pushability enhanced catheter" (column 9, lines 39-51) as represented in FIG. 6 of von Hoffmann. FIG. 6 illustrates

the catheter comprising a removable strength support 42 which "enhances the column strength of the catheter during the introduction step" (id.).

In contrast, the aspiration catheter of the present invention does not provide the coexistence of the guidewire (indicated by the guidewire lumen 110) and the core wire 101 (see FIG. 1 and 2 of present application).

One of ordinary skill in the art would also understand that the core wire in the catheter of the present invention is different from the column support 42 of von Hoffmann. The kinking resistance of the catheter of the present invention is effective from the point of view that the possibility of kinking in the catheter shaft can be reduced when it is inserted into a guiding catheter from outside the body. This means, that in the case of a high-speed exchangeable catheter such as according to the present invention, the guidewire is present only in the tip portion of the catheter. Therefore, when the aspiration catheter of the present invention is inserted into a guiding catheter, if the strength of the shaft is not sufficient, the aspiration catheter would be kinking around the inserting portion of the guiding catheter. Thus, it would be difficult to insert the aspiration catheter into the guiding catheter.

On the other hand, the catheter according to von Hoffmann is inserted into a guiding catheter, and the guidewire is present over the whole length of the catheter. This presence over the whole catheter length provides the required strength and pushability. For that reason the sufficient strength of the shaft of the catheter of von Hoffmann is based on the presence of the guidewire alone, and not the required ratio of diameters.

Von Hoffmann does not teach or suggest the ratio of the diameters required by claim 1, and does not to recognize any advantage arising from the ratio. Accordingly, the required ratio of diameters are not ascertainable or obviated by von Hoffmann.

Concerning Bagaoisan, it is generally directed to aspiration catheters having radiopaque markers incorporated into distal ends of the catheters. Visual markers

are incorporated into the proximal end of the catheters to facilitate their positioning within the body. According to Bagaoisan, the catheters are provided with varying flexibility along the length of the shaft, such that they are soft and flexible enough to be navigated through the vasculature of a patient without causing damage, but are stiff enough to sustain the axial push required to position the catheter properly and to sustain the aspiration pressures. Support mandrels and support sheaths may also be added to impart additional strength to the length of the catheter. (Abstract).

Bagaoisan likewise does not teach or suggest, at least, the "diameter" limitations of claim 1. Bagaoisan provides an over-the-wire catheter, as with von Hoffmann (col. 8, lines 32-37; FIGS. 2-3). However, Bagaoisan does not teach or suggest the required ratio of a maximum outer diameter of the core wire and a minimum inner diameter of the aspiration lumen located on the distal side (id.). Moreover, as with von Hoffmann, that a person of ordinary skill in the art could not have derived the required ratio of claim 1 from the over-the-wire catheter.

Bagaoisan further provides a single operator catheter (col. 8, lines 47-65; FIGS. 5-7). Relating to the single operator catheter, Bagaoisan likewise does not teach or suggest the required ratio. Moreover, Bagaoisan does not teach or suggest an advantage arising from the ratio between the a maximum outer diameter of the core wire and a minimum inner diameter of the aspiration lumen located on the distal side. On the contrary, Bagaoisan teaches the strength of the catheter arising from the material used and mandrels and sheaths added. Since advantages of the required ratio of diameters are not seen in Bagaoisan, the required ratio is not ascertained from that reference. Thus, Bagaoisan cannot obviate the required limitations of claim 1.

For the above reasons, claim 1 of present invention is patentable over von Hoffmann and Bagaoisan.

CONCLUSION

This application is now in condition for allowance. The Examiner is invited to contact the undersigned to resolve any issues that remain after consideration and entry of this amendment. Any fees due with this response may be charged to our Deposit Account No. 50-1314.

Respectfully submitted,
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Date: December 7, 2009

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